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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY	DOCKET NO.
09/374,935	08/16/99	OPPERMANN	H	STK-077

021323 HM22/1214
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EXAMINER

ROMEO, D

ART UNIT	PAPER NUMBER
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1647

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DATE MAILED:

12/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/374,936

Applicant(s)
Oppermann et al.

Examiner
David Romeo

Group Art Unit
1647



☒ Responsive to communication(s) filed on 16 Aug 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-17 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a protein comprising a dimer wherein the monomers are
5 chimeras of TGF- β superfamily members, classified in class 530, subclass 350.
- II. Claims 8-14, to the extent that they are drawn to a recombinant method of protein
synthesis, classified in class 435, subclass 69.7.
- III. Claims 9-14, to the extent that they are drawn to an enzymatic method of protein
synthesis, classified in class 435, subclass 68.1.
- 10 IV. Claims 9-14, to the extent that they are drawn to a non-recombinant method of
protein synthesis, classified in class 530, subclass 333.
- V. Claims 15-16, drawn to a method of tissue regeneration, classified in class 514,
subclass 12.
- VI. Claim 17, drawn to an immunoassay, classified in class 435, subclass 7.1.

15 2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be

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made by another and materially different process (MPEP § 806.05(f)). In the instant case I could be made with III or IV.

Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be
5 used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case I could be made with II or IV.

Inventions IV and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be
10 used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case I could be made with II or III.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the
15 product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case I could be used in vitro for the structure-function analysis of a TGF- β superfamily member or could be used in VI.

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Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

5 § 806.05(h)). In the instant case I could be used in vitro for the structure-function analysis of a TGF- β superfamily member or could be used in V.

The following pairwise combinations of methods are independent and distinct, wherein each member of a pair performs different functions, using different starting materials and/or process steps: II and each of III-VI; III and each of IV-VI; IV and each of V-VI; V and VI.

10 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the searches required are not coextensive, restriction for examination purposes as indicated is proper.

15 5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Claims 1-17 are generic to a plurality of disclosed patentably distinct species comprising a single species represented by:

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a single species selected from the group consisting of

- a. a finger 1 subdomain derived from a second, different member of the TGF- β superfamily; and
- b. a finger 1 subdomain derived from a third, different member of the TGF- β superfamily; and,

a single species selected from the group consisting of

- c. a heel subdomain derived from a second, different member of the TGF- β superfamily; and,
- d. a heel subdomain derived from a third, different member of the TGF- β superfamily.

in combination with,

- e. a finger 2 subdomain derived from a first member of the TGF- β superfamily;
- f. a conserved C-terminal cysteine domain.

Applicants can elect a group to be examined by specifying a single species of either a or b, a single species of either c or d, and the species e and f. For example, a proper election would be a, c, e, and f.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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Each of the species is independent and distinct, wherein each can be manufactured independently of the other and used for independent and distinct purposes.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Claims 1-17 are generic to a plurality of disclosed patentably distinct species comprising a single disclosed species of TGF- β superfamily member from which the finger 1 subdomain is derived, a single disclosed species of TGF- β superfamily member from which the finger 2 subdomain is derived, a single disclosed species of TGF- β superfamily member from which the heel subdomain is derived, and a single disclosed species of TGF- β superfamily member from which the conserved C-terminal cysteine domain is derived.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed, and consonant with the election of species in the preceding species election.

Each of the species is independent and distinct, wherein each can be manufactured independently of the other and used for independent and distinct purposes.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission
5 may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Claim 10 is generic to a plurality of disclosed patentably distinct species comprising the species listed in claim 10.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed, and consonant with the election of species in the preceding species
10 elections.

Each of the species is independent and distinct, wherein each can be manufactured independently of the other and used for independent and distinct purposes.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to
15 be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Claims 15, 16 are generic to a plurality of disclosed patentably distinct species comprising the species listed in claim 16.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed, and consonant with the election of species in the preceding species elections.

Each of the species is independent and distinct, wherein each performs different functions, using different starting materials and/or process steps, and/or with different outcomes.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 6:45 A.M. TO 3:15 P.M.

5 IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

10

David Romeo
DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DECEMBER 12, 2000